PARCUS Medical, LLC

SURGICAL INNOVATION >> VALUE DRIVEN

SEP 30 2009

510(k) Summary

Submitter: Parcus Medical, LLC
839 South Neenah Ave.
Sturgeon Bay, WI 54234

Company Contact: Barton Bracy
Phone: (920) 746-2972
Fax: (920) 746-8665

Date Prepared: April 13, 2009

Trade Name: Parcus PEEK CF Interference Screw

Common Name: Interference Screw

Classification Name: Fastener, Fixation, Non-Degradable, Soft Tissue
21 CFR 888.3040 – Product Code HWC and MBI

Predicate Devices:

- Parcus Titanium Interference Screws (K083619)
- Smith & Nephew PEEK Interference Screws (K083226)

Device Description:

The Parcus PEEK CF Interference Screw is a cannulated, threaded, tapered fastener for use in interference fixation of ligaments and tendons in patients requiring ligament or tendon repair. The device is made from Carbon Fiber Reinforced Polyetheretherketone (PEEK CF) and is available in sizes ranging from 7-12mm in diameter and 20-35mm in length.

Intended Use:

The Parcus PEEK CF Interference Screw is indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.

Substantial Equivalence Summary:

The Parcus PEEK CF Interference Screws are essentially the same as the Parcus Titanium Interference Screws aside from the difference in material.

The only difference between the materials for the Parcus PEEK CF Interference Screw and the Smith & Nephew PEEK Interference Screw is that the Parcus Interference Screw is carbon reinforced. Carbon fibers have been used clinically for more than 20 years as a reinforcement component for implant materials without obvious leachable-related biocompatibility reactions.

Furthermore, there are currently several medical device implants on the market made from PEEK CF (e.g. Zimmer Spine BAK® Vista® Radiolucent Interbody Fusion System and the Depuy Spine OCELOT™ Stackable Cage System).

Therefore the Parcus PEEK CF Interference Screw is substantially equivalent to the predicate devices listed above in which the basic features and intended uses are the same. Any differences between the PEEK CF Interference Screw and the predicate devices are considered minor and do not raise questions concerning safety and effectiveness.

Summary Performance Data:

The pull out strength and insertion torque was measured for the smallest (7mm) and largest (12mm) Parcus PEEK CF Interference Screws as well as an intermediate size. Test results were compared to the results of the corresponding size of Parcus Titanium Interference Screws and demonstrated substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

SEP 30 2009

Parcus Medical, LLC
c/o Mr. Barton Bracy
VP Marketing and Product Development
839 South Neenah Avenue
Sturgeon Bay, Wisconsin 54235

Re: K091093
Trade/Device Name: Parcus PEEK CF Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI
Dated: September 23, 2009
Received: September 30, 2000

Dear Mr. Bracy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091093

Device Name: Parcus PEEK CF Interference Screw

Indications for Use:

The Parcus PEEK CF Interference Screw is indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.

Prescription Use __X__ AND/OR Over the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091093